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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,430	01/12/2001	Lee R. Bolduc	105-C1	1423

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3773

MAIL DATE	DELIVERY MODE
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09/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/759,430	Applicant(s) BOLDUC ET AL.	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-30 and 36-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17, 19-30, 36, 38, 39 and 45-72 is/are rejected.
- 7) ☒ Claim(s) 18, 37 and 40-44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed on 6/9/08 has been entered into the application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

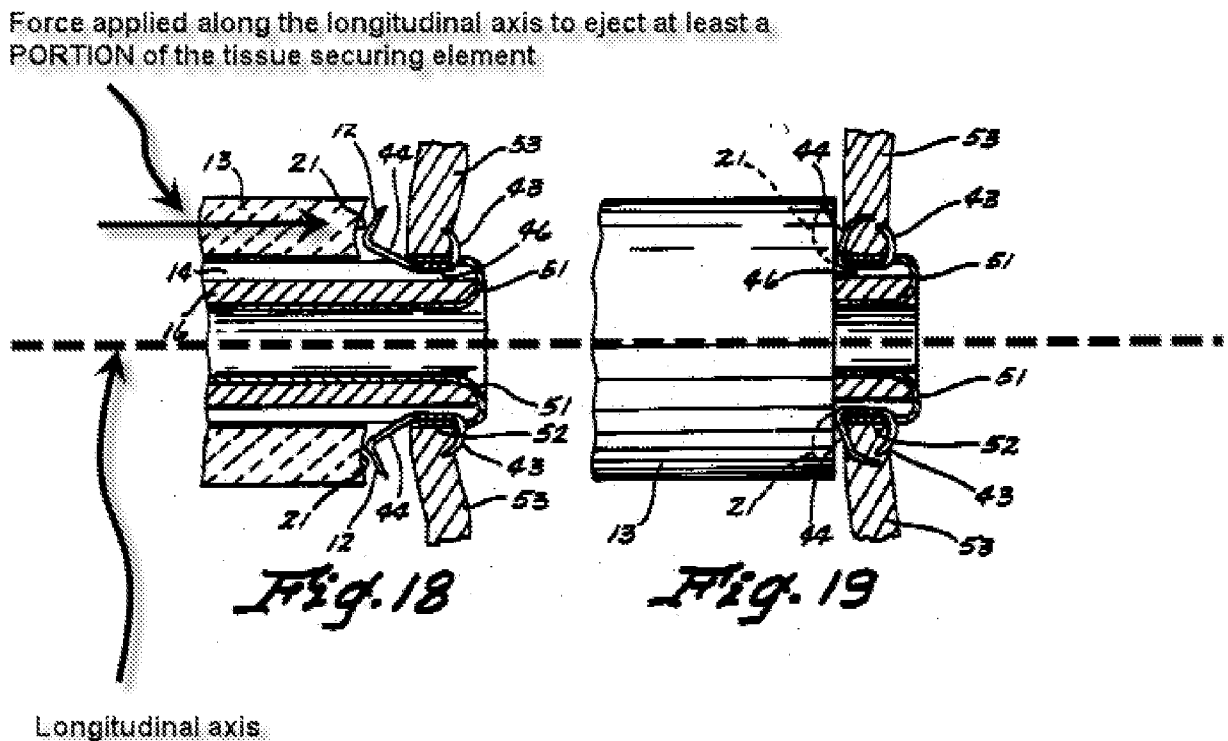
4. Claims 14-17, 19-30, 36, 38, 39 and 45-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,234,447 to Kaster et al. in view of US 5,830,222 to Makower.

Kaster teaches a method for an end-to-side anastomosis comprising the steps of providing an anastomosis device **(10,12)** having a plurality of openings (or slots defined in the core unit **14** having openings to secure the staple **12** within the sleeve **12**; also viewed as the means for holding the tissue securing elements); and a plurality of tissue securing elements having a first end a second end **(44,43)** that can be configured from an undeployed configuration to a deployed configuration; holding the plurality of tissue

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securing elements in the undeployed configuration (Fig. 14); inserting the first end through the second hollow tissue (Fig. 17); wherein the tissue securing elements are ejected from the delivery device after deployment; permitting the plurality of the tissue securing element to move from the undeployed configuration to the deployed configuration (transitioning from Fig. 17-19); wherein the first end of the tissue securing elements contact the inner surface of the second hollow tissue and the second end of the tissue securing element contact the outer surface of the second hollow tissue (end of transition shown in Fig. 19), wherein the first end of the tissue securing elements are permitted to assume the deployed configuration prior to the second end (Fig. 17); wherein the anastomosis is formed between a first blood vessel and a second blood vessel (which could be the aorta since the aorta is blood vessel); wherein both the first and second hollow tissues are compressed; wherein the first hollow tissue is everted prior to insertion to about 90 degrees, more or less (Fig. 15 and depending on the base of the angle); wherein the distal end of the first hollow tissue is compressed against the outer surface of the second hollow tissue (Fig. 17); wherein the first end of the tissue securing elements is inserted from an exterior surface toward the interior surface (since the tissue is everted; Fig. 15); wherein the device further comprises a hub having a bore (the diameter of element **46**) that receives the first hollow tissue; wherein the device comprises a body (element **46** can also be viewed as a body/sleeve); wherein the anastomosis device or the delivery device is removed after delivering the securing elements, wherein the anastomosis device comprises a plunger or mandrel **16** for delivering the securing elements; and wherein the anastomosis device has a bore and

the plurality of openings communicate with each other via the bore (see Fig. 5); wherein
the anastomosis device has a longitudinal axis, and a force is applied along the
longitudinal axis to the tissue securing elements (see figure below).



Kaster discloses all the limitation of the claimed invention except for the device being made of a material that is biased from an unbiased configuration to a biased configuration, and wherein the first ends of the tissue securing elements do not pierce the inner wall of the second hollow tissue structure.

However, Makower discloses a very similar anastomosis device (see Figs. 9, 9B, and 9C), which applies clips to connect hollow tissue structures, but teaches that the clips should be made out of shape memory materials. Makower teaches that a

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"passive" application of clips (col. 7, lines 35-37), in which the clips are merely permitted to move from a biased configuration to an unbiased configuration, is a "simplified" way of applying clips to tissue (col. 7, line 37). Makower also discloses a clip tissue securing device that does not pierce the tissue to which the clip attaches thereto.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methodology of Kasper to have the tissue securing elements be made of a shape memory material that moves from a biased configuration to an unbiased configuration since such method is well-known in the art and provides a simpler way of connecting tissues, as disclosed by Makower.

Furthermore, it would be obvious to modify the methodology of Kaster as cited above since the use of a known technique (self-deploying tissue securing elements) to improve similar devices (the device of Kaster) in the same way will provide predictable results.

KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

With regards to the first end of the tissue securing element not piercing the wall of the tissue, one of ordinary skill in the art would have found it obvious to modify the tissue securing elements of Kaster to have non-pierceable first ends as disclosed by Makower, since simple substitutions of one known element for another known element will also provide predictable results, especially since both types of securing elements are used to secure tissue (see cited case law to KSR).

Allowable Subject Matter

5. Claims 18, 37 and 40-44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

6. Applicant's arguments filed 6/9/08 have been fully considered but they are not persuasive.

The applicant's main argument is directed towards the Kaster reference allegedly failing to teach the amended limitations of the independent claims, which is summarized as follows: "wherein the anastomosis device has a longitudinal axis, and a force is applied along the longitudinal axis to the tissue securing elements". However, as shown in the attached figure above, Kaster discloses an anastomosis device having a longitudinal axis, wherein a force is applied along said axis via sleeve 13 to eject at least a portion of the tissue securing element from the opening.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezó whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezó/
Primary Examiner, Art Unit 3773